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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,640	02/25/2002	Koichi Masuda	047940-0139	3691
23524	7590	05/17/2005		
FOLEY & LARDNER				EXAMINER
150 EAST GILMAN STREET				NAFF, DAVID M
P.O. BOX 1497				ART UNIT
MADISON, WI 53701-1497				PAPER NUMBER
				1651

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/084,640	MASUDA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 March 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 and 20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8 and 15-19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

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**DETAILED ACTION**

An amendment of 3/21/05 amended claims 1, 2, 4, 15, 16 and 18, and canceled claim 14.

Claims in the application are 1-13 and 15-20.

5       Claims 9-13 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/27/04.

10      Claims 1-8 and 15-19 are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 1-18 and 15-19 are rejected under 35 U.S.C. 103(a) as 15 being unpatentable over Matsumoto et al (International Conference, Bone Morphogenetic Proteins 2000, June 7-11, 2000) or Matsumoto et al (47<sup>th</sup> Annual Meeting , Orthopaedic Research Society, February 25-28, 2001) (newly applied) in view of Kang et al (2001/0006948) (newly applied), and if necessary in further view of Masuda et al (6,451,060 20 B2).

The claims are drawn to producing engineered tissue by transfecting intervertebral disc cells with exogenous nucleic acid, culturing the intervertebral disc cells in a medium followed by culturing the cells on a semipermeable membrane in the presence of a 25 growth factor, which can be osteogenic protein-1 (OP-1). The medium

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can be an alginate medium. Also claimed, is intervertebral disc tissue resulting from the method, and a method of implanting the intervertebral disc tissue produced by the method to repair intervertebral disc damage.

5 Matsumoto et al (2000) and (2001) disclose producing engineered intervertebral disc tissue for implanting to repair damaged intervertebral disc using a two step tissue engineering method referred to as the alginate-recovered-chondrocyte method (ARC method). This method involves culturing intervertebral disc cells in an 10 alginate medium to produce cells surrounded by a cell-associated matrix, and culturing the cells surrounded by cell-associated matrix on a semipermeable membrane in the presence of OP-1 growth factor to produce intervertebral disc tissue on the membrane. This method for producing intervertebral disc tissue is the same as presently claimed 15 except for initially transfecting the intervertebral disc cells with exogenous nucleic acids.

Kang et al disclose (paragraph 0012) gene transfer to intervertebral disc cells. A nucleic acid sequence encoding the gene is introduced into the cells so the gene will be expressed in the 20 cells to produce a product such as OP-1 growth factor (paragraph 0049, line 32 of the paragraph, and claims 17-19).

Masuda et al disclose the ARC method, which contains the same steps and conditions as Matsumoto et al (2000) or (2001), except that chondrocytes are cultured to produce cartilage tissue. Masuda et al

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disclose providing a growth factor such as OP-1 during culturing the cells on a membrane.

It would have been obvious to transfect the intervertebral disc cells cultured in the method of Matsumoto et al (2000) or (2001) with 5 an exogenous nucleic acid that encodes the cells to produce a growth factor such as OP-1 as suggested by Kang et al transfecting intervertebral disc cells to produce OP-1. The transfected intervertebral disc cells not requiring the addition of OP-1 in the method of Matsumoto et al (2000) or (2001) since OP-1 is produced by 10 the cells, and the transfected cells having the ability to produce OP-1 after implanting would have been motivation to transfect the intervertebral disc cells in the method of Matsumoto et al (2000) or (2001). If needed, steps of the ARC method would have been apparent from Masuda et al. The conditions of dependent claims are disclosed 15 by the references, or would have been obvious therefrom.

***Claim Rejections - 35 USC § 103***

Claims 1-8 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda et al (6,451,060 B2) in view Matsumoto et al (2000) or (2001) and Kang et al.

20 The invention, Masuda et al, Matsumoto et al and Kang et al are described above.

It would have been obvious to use the method of Masuda et al to produce intervertebral disc tissue by substituting intervertebral disc cells for the chondrocytes in the method of Masuda et al as suggested 25 by Matsumoto et al (2000) or (2001) using the same type of method as

Masuda et al to produce intervertebral disc tissue for implanting.

Kang et al would have suggested transfecting the intervertebral disc cells with exogenous nucleic acid to produce OP-1 since OP-1 is used as a growth factor when culturing cells in the methods of Masuda et al and Matsumoto et al. Advantages of transfected intervertebral disc cells producing OP-1 without adding OP-1 and producing OP-1 after the cells are implanted would have been motivation to transfect the cells.

#### ***Response to Arguments***

Applicants argue that the claims have been amended to require 10 transfected the intervertebral disc cells with exogenous nucleic acid, which is not disclosed by Matsumoto et al or Masuda et al. However, for reasons set forth above, Kang et al would have suggested transfecting the intervertebral disc cells with exogenous nucleic acid.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the 25 shortened statutory period will expire on the date the advisory action

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is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, 10 the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) 15 system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
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